DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration
Kansas City District
Southwest Region
11630 West 80th Street
Lenexa, Kansas 66214-3340

Telephone: (913) 752-2100

August 1, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
Ref. KAN 2003-009

Mr. Robert S. Kopriva
Senior VP, President & CEO
Sara Lee Foods
10151 Carver Road
Cincinnati, OH 45242-4719

Dear Mr. Kopriva:

An investigation of your medicated feed mill, Bil-Mar Foods Division of Sara Lee, located at 501 Seneca Street, Storm Lake, Iowa conducted by Food and Drug Administration (FDA) investigators on April 17, 18, and 22, 2003 found significant deviations from the Current Good Manufacturing Practice (cGMP) regulations for Medicated Feeds [Title 21 Code of Federal Regulations, Part 225 (21 CFR 225)]. Such deviations cause feeds being manufactured at this facility to be adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found:

- that you were unable to verify that your batch production records were checked by a responsible individual at the end of the working day in which the product was manufactured to determine whether all required production steps had been performed. Furthermore, your batch production records do not reflect that a required production step -- pelleting -- was performed. Failure to determine if all required production steps were performed is a significant deviation from 21 CFR 225.102(b)(4).

- that you stored expired and unlabeled product in the mixing area, a violation of 21 CFR 225.42(b)(4).

In addition, we remind you that for feeds requiring a medicated feed mill license for their manufacture and marketing, 21 CFR 225.558 requires that at least three representative samples be collected and assayed at periodic intervals. Such samples should be collected from the

finished form of the final product. A sample taken from a mixer, for instance, is not representative because it has not been through all of the manufacturing steps.

The above is not intended as an all-inclusive list of cGMP violations. As a manufacturer of medicated feeds you are responsible for assuring your overall operation and the products you manufacture and distribute are in compliance with the Act and implementing regulations.

You should take prompt action to correct these cGMP violations. Failure to effect prompt and permanent corrective actions may result in regulatory and/or administrative sanctions including seizure, injunction and notice of opportunity for a hearing on a proposal to withdraw approval of your Medicated Feed Mill License under section 512(m)(4)(B)(ii) of the Act and 21 CFR 515.22(c)(2). This letter constitutes official notification under the law and provides you an opportunity to correct the deficiencies in your operations.

We also have two other issues that resulted from the subject investigation that you should address. Analytical results of a sample that was collected during this investigation show that medicated feed manufactured at your facility had more than the allowable limits of drug substance. The super potent medicated feed has between 164% and 244% of the label claim. These results were provided to your Storm Lake, Iowa facility in a notice dated May 1, 2003. We request you review your records, any investigations and assay results and report to us concerning this issue.

The investigation also revealed that your firm uses a computerized batching system to mix the feed, and that many of your firm's records are generated and maintained electronically. We take this opportunity to remind you that if you rely on a computer system to perform and monitor manufacturing steps and keep records, you must make sure that the system is actually capable of performing the manufacturing steps as well as collecting and/or reporting all records required by the medicated feed cGMP regulations. Additionally, electronic records are regulated by 21 CFR 11, and we have enclosed a copy of those regulations.

We are in receipt of a response from your firm dated May 6, 2003 and signed by Michael R. Westphal. We reviewed and considered your firm's response during preparation of this Warning Letter.

You should notify this office in fifteen (15) working days of the steps you have taken to achieve and maintain compliance with the regulations. In your response, please explain the steps your firm has taken to address the super potent monensin-medicated feed analytical results, as well as your intentions to address the computer-related issues. Please send your

response to Ralph J. Gray, Compliance Officer, at the above address.

Sincerely,

Clarence R Pendleton

for/ Charles W. Sedgwick
District Director
Kansas City District Office

cc: Michael R. Westphal
Executive Director/Grow Out and Procurement
Bil-Mar Foods Division of Sara Lee
501 Seneca Street
Storm Lake, IA 50588